

REMARKS:

Claims 1-13, 15-19, 21-26, and 28-29 have been cancelled, while claims 14 and 27 have been amended. Hence, claims 14, 20, and 27 currently are pending.

Claims 14, 15, 18, 20, and 27 were rejected under 35 U.S.C. 102(e) as unpatentable over Hichems et al. (U.S. Patent No. 6,468,953; hereinafter Hichems) in view of Kasting, Jr. et al. (U.S. Patent No. 5,368,815; hereinafter Kasting). The Examiner also rejected claim 27 under 35 U.S.C. 103(a) as unpatentable over WO02/32467 (hereinafter the '467 reference) in view of Kasting.

In response, claim 14 has been amended to recite:

A method of supplementing a cleaning and sterilizing process ~~for~~ of an endoscope ~~soiled item~~ having bio-contaminants in a sterilizing apparatus having a water storage tank, comprising the steps of:

- a. applying a chemical sterilizing agent to a clean endoscope item to achieve high-level disinfection; ~~and~~
- b. ~~providing a final rinse of the high-level disinfected item with ozonated, treating filtered water stored in said tank to degrade remaining biomatter resulting from contamination of said water, wherein ozone is continuously added to the water in the tank by re-circulation past the a venturi; and~~
- c. providing a final rinse of the high-level disinfected endoscope with said ozonated, filtered water stored in said tank, wherein said water is sterilized by said treating but said endoscope is not exposed to freshly generated ozone by said final rinse.

Support for these amendments is found, among other places, at page 1, line 10 (disclosing endoscopes), page 7, line 2 (disclosing that methods of the invention are used in conjunction with sterilizing apparatus), page 15, lines 29-30 (referring to a sterilizing device having water stored in a tank), page 7, lines 13-14 (disclosing that the invention may include "final rinses with ozone or water that has been ozonated"), and page 15, line 30, to page 16, lines 1 and 2

(which disclose "The ozone is continuously added to the water in the tank by re-circulation past the venturi. Thus, the sterility of the water is ensured without exposing the reprocessor components or items to be cleaned to a constant supply of freshly generated ozone.").

Hichems discloses various sterilizing methods using chemical sterilants. Kasting discloses an apparatus and method for sanitizing PET bottles through delivering water that has been injected with ozone sufficient to sanitize (col. 2, lines 43-45; also, all independent claims recite either "a process for sanitizing articles with ozonated water" or "injecting ozone into the supplied water sufficient for sanitizing"). Indeed, Fig. 2 of Kasting shows that the ozone injecting venturi 48 is located in line with the only supply line that goes to the spray bar, meaning that all water is freshly ozonated just before being sprayed onto the article being sanitized. Moreover, an ozone sensor 52 that shuts down the sprayer if low ozone in the water is detected is disposed between the venturi and the spray bar, indicating that it is undesirable to simply spray the bottles with sterile water that does not itself possess sanitizing ozone levels. Thus, it is clear that Kasting teaches the use of water that is so thoroughly and freshly ozonated that it effects sanitation of the article being rinsed.

Accordingly, when combined with Hichems' use chemical sterilizing agents as the Examiner suggests, Kasting's apparatus and method would be seen by one of ordinary skill to provide only a "backup" sanitizing rinse.

While one aspect of the applicant's invention involves water containing amounts of ozone sufficient to sanitize or degrade chemical, another aspect is to simply assure that the rinse

water is sanitized (so that it will not re-contaminate) without exposing an already cleaned and high-level disinfected item (especially delicate endoscopes) to potential damage caused by additional exposure to ozone. Thus, the amended claims recite a final water rinse to an already clean and high-level disinfected endoscope that does not expose the endoscope to freshly generated ozone.

Given the very short duration of ozone, the method of the invention both ensures a supply of freshly sterilized water is ready for immediate use from the tank and minimizes the possibility of damage caused by fresh ozonation. On page 4 of the applicant's written disclosure this very issue is discussed:

Nonetheless, the strongly oxidative qualities of ozone also present problems in that the use of ozone for the cleaning and disinfecting of items will often result in permanent damage to the item, especially if it is exposed to ozone for long periods while attempting to completely clean and decontaminate all surfaces. Thus, while ozone applications to water and water line disinfection are now fairly common, these methods have not become widespread in other sterilization applications because they rely on a treatment system that reticulates ozonated water through the entire treatment area during repeated cleaning cycles in order to achieve and maintain disinfection. Such constant treatment is not possible for most items (and especially medical items) due to the damage that continual or repeated exposure to ozone would cause.

Hence, the applicant's Summary of the Invention on page 7 (lines 4-6) states "Yet another object of the invention is to provide a method for ensuring the sterility of water used to rinse endoscopes or other items after cleaning and sterilization have taken place" and the Detailed Description discloses "Still another embodiment involves treating rinse water with ozone to prevent re-contamination of the item" on page 8 (lines 24-25). Finally, page 15, line 30, to page 16, lines 1 and 2 teaches that "The ozone is continuously added to the water in the tank

by re-circulation past the venturi. Thus, the sterility of the water is ensured without exposing the reprocessor components or items to be cleaned to a constant supply of freshly generated ozone." In other words, claim 14 recites a method that uses a final rinse of water that is itself sterilized but that does not sanitize the endoscope being rinsed. This prevents re-contamination of the endoscope from the rinse water (a huge problem per applicant's previously submitted Declaration and evidence) while minimizing damage that could be wrought by oxidation from freshly ozonated water to an already high-level disinfected endoscope.

Regarding the rejection of claim 27 over Kasting and the '467 reference, claim 27 now recites, in relevant part, that the water is sterilized by said re-circulation, but said apparatus components are not exposed to freshly generated ozone (with support for this amendment being found per the description above). Thus, cross-contamination from the water supply is prevented while minimizing damage to the sterilizer components. Because both Kasting and the '467 reference exclusively teach the use of freshly ozonated water (i.e., water with sufficient ozone for disinfecting an item), the combination of these references do not disclose or suggest claim 27 as amended.

In view of the foregoing, as well as the previously submitted objective evidence of unexpected results, long-felt need, failure of others, and skepticism of experts, the applicant respectfully submits that the claims of the present invention are both novel and unobvious in view of the cited art. Therefore, reconsideration of the rejections is respectfully requested.

Except for the fee provided herewith for a 3-month extension of time, no fee is believed to have been incurred for this amendment. Should there be any unforeseen costs, please charge our Deposit Account No. 17-0055.

Respectfully submitted,

Quarles & Brady, LLP

A handwritten signature in black ink, appearing to read 'G. Milczarek-Desai', written in a cursive style.

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